



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF APPEALS AND INTERFERENCES

In re application of

:

Kanji TAKADA et al.

Group Art Unit.: 1616

Serial No.: 09/787,612

Examiner: Sharmila S. Gollamudi

Filed: March 20, 2001

Title:

ORAL DRUG DELIVERY SYSTEM FOR ENHANCING THE BIOAVAILABILITY OF ACTIVE FORM OF GLYCYRRHIZIN

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

MAIL STOP APPEAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the paper mailed on June 17, 2005, please consider the following.

Applicants filed an Appeal Brief on July 20, 2004, with the impression that the amendments after final were entered based on the Advisory Action dated May 4, 2005, where the box indicating that for purposes of an appeal the amendments will be entered was checked. The Examiner indicated in a paper mailed September 27, 2004, that the amendments after final were not entered. A replacement Appeal Brief was then submitted on February 17, 2005, appealing some (but not all) of the claims pending prior to final.

Then followed the Notice of Non-Compliant Appeal Brief dated June 17, 2005, alleging that the claims appendix is defective because claims 11-13, 15, 19 and 27 are in the appendix while claims 10-19 and 27 are rejected.

Please note the clear statement in the "Status of Claims" section of the Appeal Brief stating that "Claims 27, 11, 13 and 15 are on appeal." Thus, claims 11, 13, 15 and 27 were included in the claims appendix along with any claim any of these claims depend from, i.e., claims 12 and 19 in addition. Thus, the claims appendix correctly contains "a copy of the claims

<u>involved in the appeal</u>," (emphasis added) which is what is required by 37 CFR § 41.37(c)(1)(viii). Therefore, there is no error nor is there non-compliance.

Nevertheless, to avoid the possibility to having the allegation of non-compliance remain an issue, attached is a new claims appendix which list all the rejected claims, i.e., claims 10-19 and 27. Applicants reiterate that the claims involved in the appeal however are claims 11-13, 15, 19 and 27 which are contained in the claims appendix of the Appeal Brief filed on February 17, 2005.

Reconsideration is respectfully requested.

Respectfully submitted,

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Attorney Docket No.: AKA-269

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(viii) CLAIMS APPENDIX

- 10. A device for colon-targeted oral delivery of glycyrrhizin comprising a shaped core containing an amount of glycyrrhizin, said shaped core being made of a suppository base comprising glyceride that melts or liquefies at the body temperature, and a coating film of ethylcellulose enclosing said shaped core and having a film thickness whereby when the device is transported through the digestive tract to the colon, the film enclosing the liquefied core ruptures selectively in the colon by the internal pressure generated by the peristalsis of the intestine.
- 11. The device according to claim 19, wherein said amount of glycyrrhizin is in excess of the amount needed for compensating for the hydrolysis thereof by the intestinal flora.
- 12. The device according to claim 19, wherein said coating film is formed by dipping the shaped core in a solution of ethylcellulose.
- 13. The device according to claim 12, wherein said shaped core is dusted with a powder to prevent from sticking before dipping.
- 14. The device according to claim 19, wherein said shaped core further contains an absorption promoter for glycyrrhizin.
 - 15. The device according to claim 13, wherein the powder is talc.
- 16. The device according to claim 14, wherein absorption promoter is an organic acid, a surfactant, a chelating agent, or a mixture thereof.
- 17. The device according to claim 19, wherein the device contains 10 to 1,000 mg of glycyrrhizin.

- 18. The device according to claim 19, wherein the device contains 100 to 800 mg of glycyrrhizin.
- 19. A device for colon-targeted oral delivery of glycyrrhizin comprising a shaped core containing an amount of glycyrrhizin, said shaped core being made of a glyceride suppository base that melts or liquefies at the body temperature, and a continuous coating film of ethylcellulose enclosing said shaped core and having a film thickness whereby when the device is transported through the digestive tract to the colon, the film enclosing the liquefied core ruptures selectively in the colon by the internal pressure generated by the peristalsis of the intestine.
- 27. A device for colon-targeted oral delivery of glycyrrhizin consisting of a shaped core containing an amount of glycyrrhizin, said shaped core being made of a suppository base comprising glyceride that melts or liquefies at the body temperature, and a coating film of ethylcellulose enclosing said shaped core and having a film thickness whereby when the device is transported through the digestive tract to the colon, the film enclosing the liquefied core ruptures selectively in the colon by the internal pressure generated by the peristalsis of the intestine.